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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,344	01/14/2002	Sheena M. Loosmore	1038-1221 MIS:jb	7370

24223 7590 06/24/2005

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,344	LOOSMORE ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 25-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 25-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed April 14, 2005 has been entered. The examiner acknowledges the amendment to the specification. Claim 25 has been amended. Claims 1-24 have been cancelled. Claims 25-27 are under consideration in the office action.

Withdrawal of Objections and Rejections

2. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) The objection of claim 24;

b) The written description rejection of claims 14 and 18-27 under 35 U.S.C. 112, first paragraph;

c) The deposit rejection of claim 23 under 35 U.S.C. 112, first paragraph;

d) The rejection of claims 14 and 18-27 under 35 U.S.C. 112, second paragraph,

e) The nonstatutory double patenting rejection of claims 14,18-19 and 24;

f) The rejection of claims 14 and 18-22 under 35 U.S.C. 102(b) as being anticipated by Holland et al; and

g) The rejection of claims 24-27 under 35 U.S.C. 103(a) as being unpatentable over Schryvers (US Patent 5, 141,743) in view of Gerlach et al.

Response to Arguments

3. Applicant's arguments filed April 14, 2005 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

4 The nonstatutory double patenting rejection of claims 25-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,922,562 in view of Loosmore et al., WO 96/40929 is maintained.

The examiner acknowledges applicants intention to file the appropriate terminal disclaimer when allowable subject matter has been agreed upon, however the rejection must stand until the double patenting issue is resolved.

New Grounds of Rejection

Claim Objections

5. Claim 25 is objected to because of the following informalities: The claim refers to "....a pharmaceutically acceptable carrier therefor", however it is suggested that the phrase be "...a pharmaceutically acceptable carrier thereof". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 25-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims drawn to an immunogenic composition comprising at least one synthetic peptide having no less than six amino acids and no more than 150 amino acids and a pharmaceutically acceptable carrier therefor, wherein the synthetic peptide is comprised of the amino acid sequence SEQ ID NO:74 or SEQ ID NO:85 and produces an immune response when administered to a host.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties,

functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.,* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe,* 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The claims and specification recite immunogenic compositions with particular synthetic peptides, however the specification provides no guidance as to what the upper limit of the number of synthetic peptides may be encompassed by the composition. Moreover, the composition recites open language and therefore includes a wide variety and unlimited number of additional components. Yet there is no disclosure of what other components may be included in the composition or how many of these other components may be present. The claims fail to limit the number of peptides or other components within the composition. The claims broadly recite that the immunogenic composition must only comprise at least one synthetic peptide and a pharmaceutically

acceptable carrier. Therefore all synthetic peptide having no less than six amino acids and no more than 150 amino acids are being claimed, along with all other possible components including any combination of nucleic acid molecules, recombinant proteins, and transferrin binding proteins. No specific limitations for what additional peptides or ingredients have been disclosed by the instant specification, and such unlimited additions have not taught and/or enabled by the specification.

Thus, the immunogenic compositions comprising at least one synthetic peptide having no less than six amino acids and no more than 150 amino acids and a pharmaceutically acceptable carrier therefor, wherein the synthetic peptide is comprised of the amino acid sequence SEQ ID NO:74 or SEQ ID NO:85 fail to meet the written description provision of 35 UCS 112, first paragraph. *Vas-Cath Inc. V. Mahurkar,* 19 USPQ2d 1111, make clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). There is no disclosure of immunogenic composition comprising three, four or five synthetic peptides having no less than six amino acids and no more than 150 amino acids and a pharmaceutically acceptable carrier therefor, wherein at lest one synthetic peptide is SEQ ID NO:74 or SEQ ID NO:85. Thus, the structure of the immunogenic composition is not defined. Even though claim 25 recites that the composition must comprise at lest SEQ ID NO:74 or 85, the claim does not limit the

number of other peptides that may be included in the composition. Moreover, dependant claim 26 do not limit the number of synthetic peptides; rather the claim includes the synthetic peptides of SEQ ID NO:50 and 61 along with an unlimited number of additional peptides and other components with no guidance. There is no written description of an immunogenic composition comprising these three synthetic peptides and a pharmaceutically acceptable carrier. Thus, a skilled artisan cannot envision the detailed structure of the immunogenic composition since the specification has not defined what the additional variables i.e., other synthetic peptides, proteins, adjuvants, or molecules can be. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for production.

At best the specification and claims describe the synthetic peptide, however they fail to describe the upper limit on the number of peptides that may be comprised within the composition. Moreover, there is no disclosure of what other components may or may not be included within the instantly claimed immunogenic composition. The specification fails to teach the structure or relevant identifying characteristics of a representative number of immunogenic compositions sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. Thus a skilled artisan cannot envision all the contemplated immunogenic compositions and therefore conception cannot be achieved until reduction to practice has occurred. It is noted however that applicants are not required to disclose every species encompassed by a genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of

representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli,* the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli,* 872 F.2d at 1012, 10 USPQ2d at 1618.

In view of the specification failure to disclose the identity or adequately describe an immunogenic composition comprising at least one synthetic peptide having no less than six amino acids and no more than 150 amino acids and a pharmaceutically acceptable carrier therefor, wherein the synthetic peptide is comprised of the amino acid sequence SEQ ID NO:74 or SEQ ID NO:85 and produces an immune response when administered to a host, a skilled artisan would be required to de novo locate, identify and characterize the claimed immunogenic compositions. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

New Matter

7. Claims 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for an immunogenic composition comprising at least one synthetic peptide having no less than six amino acids and no more than 150 amino acids and a pharmaceutically acceptable carrier therefor, wherein the synthetic peptide is comprised of the amino acid sequence

SEQ ID NO:74 or SEQ ID NO:85 and produces an immune response when administered to a host.

Applicant did not point to support in the specification for an immunogenic composition comprising at least one synthetic peptide comprised of the amino acid sequence SEQ ID NO:74 or SEQ ID NO:85 and a pharmaceutically acceptable carrier thereof, which produces an immune response when administered to a host with no upper limit one the number or types of peptides and additional components which can be included in said composition. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of the immunogenic composition comprising at least one synthetic peptide comprised of the amino acid sequence SEQ ID NO:74 that further comprises SEQ ID NO:50, 61 and SEQ ID NO:85 and a pharmaceutically acceptable carrier. Thus, there appears to be no teaching of said immunogenic composition with no limit on all the possible additional components which can be included. Page 9 of the instant specification only states that one active component should be included within the immunogenic composition, and fails to disclose what other types or the amount or number of additional synthetic peptides and components which may be or may not be included in the composition. Thus, it appears that the entire specification appears to fail to recite support for the newly recited immunogenic composition. Therefore, it appears that there is no support in the specification. Applicants must therefore specifically point to page and line number support for the identity an immunogenic composition comprising at least one synthetic peptide comprised of the amino acid sequence SEQ ID NO:74 or SEQ ID NO:85 and a

pharmaceutically acceptable carrier thereof, which produces an immune response when administered to a host as recited by the newly amended claims. Therefore, the new claims incorporate new matter and are accordingly rejected.

Status of Claims

8. No claims allowed.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
June 16, 2005

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